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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,060	11/27/2006	Jane Evison	2955-231	4182

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
03/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,060	EVISON, JANE	
	Examiner	Art Unit	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 46-48* is/are pending in the application.

4a) Of the above claim(s) *12,13 and 39-44 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/07 and 8/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in the reply filed on 12/24/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 40-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without specifying** traverse in the reply filed on 12/24/2008.

4. Applicant's election of (i) – (ii) ammonium acryloyldimethyltaurate / vinyl pyrrolidone as a copolymer and gelling agent; (iii) a thickening agent as not present; (iv) water as present; and (v) a cosolvent, ethanol, as present in the reply filed on 12/24/2008 is acknowledged. The elected species read upon claims 1-11 and 14-38. Claims 12-13 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without specifying** traverse in the reply filed on 12/24/2008.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 25-29 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention**.

7. Claim 25 recites the limitation "the active ingredient" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Nowhere in claim 1 is the phrase “active ingredient” recited. Accordingly, claim 25 and dependent claims 26-29 and 32-36 are rejected as indefinite.

Claim 31 contains the phrase “such as” (i.e., tetracylcines **such as** doxycyclie or minocycline, sulfa drugs **such as** suflacetamide, penicillins, etc). It is not clear whether the phrase "such as" is a limitation or whether it is merely listing disclosed examples and/or embodiments. Description of examples or preferences is properly set forth in the specification rather than the claims. Since it is unclear whether this phrase is a limitation, and thus part of the claimed invention, this phrase renders the claim indefinite.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **Claims 1-11, 14-29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Singh et al* (US 6,428,772), *Singh and Roberts* (JPET 268:144-**

151, 1993), *Hong et al* (WO 1999/39713), *Obata et al* (Int J Pharm 89:191-198, 1993), and *Loffler et al* (Household and Personal Products Industry, July 2002).

10. Instant claims 1-6 and 25 are drawn to a cosmetically acceptable skincare composition in the form of a hydroalcoholic gel dispersion, the composition comprising salicylic acid or a salt thereof (more specifically, salicylic acid – claim 25) and a gelling agent, more specifically wherein the gelling agent is ammonium acryloyldimethyltaurate / vinyl pyrrolidone (hereinafter Aristoflex AVC), and further provided that if the composition contains xantham gum then it does not contain iron trichloride.

11. Cosmetically acceptable skincare compositions comprising salicylic acid in the forms of gels, lotions, creams and solutions are well known in the art to be safe and effective especially for the treatment of acne. As specifically disclosed by *Singh et al*, "[s]alicylic acid has been approved by the U.S. Food and Drug Administration for the treatment of acne in concentrations of 0.5% to 2% by weight. Such compositions may be in the form of a gel, lotion, cream or solution" (Column 1, Lines 16-19). However, *Singh et al* also teach that "salicylic acid is sparingly soluble in water" (Column 1, Line 21). Furthemore, *Singh and Roberts* teach that nonsteroidal anti-inflammatory drugs (NSAIDs), such as salicylic acid, show low skin permeability when topically applied (Pages 148-150, Figures 3-5). Notably, *Singh and Roberts* also disclose that other NSAIDs (in addition to salicylic acid), such as diclofenac and piroxicam, similarly show low skin permeability when topically applied (Pages 148-150, Figures 3-5).

12. In the case of piroxicam, *Hong et al* teach "a hydroalcoholic gel composition which can not only decrease the external loss of piroxicam but can increase the

permeation of piroxicam through skin remarkably compared with [a] conventional hydrogel preparation" (Abstract). More specifically, the hydroalcoholic gel composition taught by *Hong et al* "comprises (a) 0.1~2% by weight of piroxicam; (b) 40~60% by weight of lower alkanol having from one to four carbon atoms; (c) 0.1~5% by weight of hydroxypropylcellulose or hydrophobic derivatives of hydroxypropylmethylcellulose, optionally comprising hydroxypropylmethlycellulose or carbomer... and (f) water" (abstract).

13. Furthermore, in the case of diclofenac, *Obata et al* demonstrate that ethanol enhances skin permeation of the NSAID by attacking the dense barrier structure of the skin (Abstract).

14. Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate a skincare composition comprising the NSAID salicylic acid in the form of a hydroalcoholic gel dispersion. The skilled artisan would have been motivated to do in view of *Singh and Roberts* - which teach that topical formulations of NSAIDs (such as salicylic acid and piroxicam) show low skin permeability - and in view of *Hong et al* which specifically teach that hydroalcoholic formulations comprising piroxicam decrease the external loss of the NSAID and increase permeation of the NSAID through the skin. Thus, the skilled artisan would have been motivated to provide salicylic acid in a hydroalcoholic gel dispersion in order to overcome the compound's low permeability. Although *Hong et al* is drawn to piroxicam, and not specifically to salicylic acid, the skilled artisan would have predicted that formulating salicylic acid in a hydroalcoholic gel dispersion would similarly enhance

the compound's skin permeation since both of the compounds are NSAIDs having similar mechanisms of action. Thus, the person of ordinary skill in the art would have predicted that a formulation which enhances the permeability of one NSAID compound (piroxicam) would also enhance the permeability of another NSAID (salicylic acid). More specifically, in view of *Obata et al*, which demonstrate that ethanol enhances skin permeation of the NSAID diclofenac by attacking the dense barrier structure of the skin (Abstract), the skilled artisan would have predicted that the hydroalcoholic gel dispersion taught by *Hong et al* (comprising ethanol (Pages 11-14, Examples 1-6 and Pages 17-8, Examples 8-18)) enhances piroxicam permeability by disrupting the skin barrier, a condition which would similarly enhance the permeation of salicylic acid. Accordingly, for all of the foregoing reasons, it would have been *prima facie* obvious to formulate the hydroalcoholic gel dispersion taught by *Hong et al* wherein the hydroalcoholic gel comprises salicylic acid (as recited by the instant claims) in place of piroxicam (as taught by *Hong et al*).

15. However, the hydroalcoholic gel dispersion taught by *Hong et al* comprises gelling agents such as "hydroxypropylcellulose or hydrophobic derivatives of hydroxypropylmethylcellulose optionally comprising hydroxypropylmethlycellulose or carbomer" (Page 5, Lines 2-4) whereas instant claims 1-6 are drawn to a hydroalcoholic gel dispersion comprising Aristoflex AVC as the gelling agent. *Loffler et al* teach Aristoflex as a gelling agent useful in hydroalcoholic gel disperstions. Specifcally, *Loffler et al* teach that "Aristoflex AVC is easy to use, as the polymer is pre-neutralized. Gelling takes place immediately when the polymer comes in contact with water"

(Paragraph 4) and that "Aristoflex AVC is particularly suitable for modern cosmetics" (Paragraph 6). Moreover, *Loffler et al* disclose that "compatibility with polar organic solvents is of interest for the formulation of hydro-alcoholic gels. Aristoflex AVC has good compatibility with polar organic solvents such as ethanol or acetone. Commercial application could be the formulation of hydro-alcoholic hair gels, antiseptic hand sanitizers or nail polish removers containing acetone" (Paragraph 9). *Loffler et al* further point out that "Aristoflex AVC can be used in a broad pH range" (Paragraph 8) and is "much more stable" to UV light and shear stress **than a typical carbomer** (Paragraphs 10-11).

16. *Loffler et al* conclude that "Aristoflex AVC… is pre-neutralized, it is easy to incorporate in any stage of the gel or emulsion formation. It has excellent stability against high shear forces and UV light. It tolerates low pH-values, high amounts of polar organic solvents and it allows formulation of emulsifier-free gels" (Final Paragraph). Thus, for all of these reasons, it would have been obvious to a person of ordinary skill in the art to formulate the hydroalcoholic gel dispersion taught by *Hong et al* using Aristoflex AVC as the gelling agent. The skilled artisan would have been motivated to do so for the reasons taught by *Loffler et al*. That is, the skilled artisan would have reasonably predicted that using Aristoflex AVC in place of the gelling agent taught by *Hong et al* would provide good stability against high shear forces and UV light, tolerate low pH values, and, significantly, high amounts of polar organic solvents such as ethanol in the formulation of hydroalcoholic gels.

17. For all of the foregoing reasons, claims 1-6 and 25 are rejected as *prima facie* obvious.

18. Instant claims 7-11 further define the amount of gelling agent, specifically wherein the composition comprises less than 5% w/w of the gelling agent (claims 7-8), more than 0.5% w/w of the gelling agent (claims 9-10), or 0.1 to 5% w/w of the gelling agent (claim 11). As stated in MPEP 2144.05:

> In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)

. As specifically, stated by *Loffler et al* regarding Aristoflex AVC, "For personal care formulations, the amount required in practice is typically in the range of 0.5-1.0%" (Paragraph 6). Accordingly, the claimed ranges overlap ranges disclosed by the prior art. As such, claims 7-11 are rejected as *prima facie* obvious.

19. Instant claims 14-16 further define the amount of water in the composition. *Hong et al* disclose specific embodiments of hydroalcoholic gels comprising in excess of 38% w/w water (Page 17, Example 8). Accordingly, instant claim 14 is rejected as *prima facie* obvious. As to claims 15 and 16, MPEP 2144.05 states that:

> Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

. In the instant case, the concentration of water in the hydroalcoholic gel composition is clearly a result-effective variable. Alterations in the amount of water would affect the viscosity of the hydroalcoholic gel and thus impact the skin feel of the composition. Accordingly, it would have been customary for an artisan of ordinary skill in the art to determine the optimal amount of water to include in the formulation in order to best achieve the desired results. See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Accordingly, claims 15-16 are also rejected as *prima facie* obvious.

20. Claims 17-19 define the cosolvent of the hydroalcoholic gel as ethanol. As discussed above, *Hong et al* teach a hydroalcoholic gel comprising "40~60% by weight of lower alkanol having from one to four carbon atoms" (Abstract). More specifically, *Hong et al* disclose specific embodiments comprising ethanol (Pages 11-14, Examples 1-6 and Pages 17-8, Examples 8-18). Accordingly, claims 17-19 are rejected as *prima facie* obvious.

21. Claims 20-24 further define the amount of cosolvent in the composition, most specifically wherein the composition comprises in excess of 30% (claims 20-23) or not more than 50% (claim 24). *Hong et al* disclose specific embodiments comprising ethanol in the amount of 50% w/w (Page 17, Example 9). As such, claims 20-24 are rejected as *prima facie* obvious.

22. Claims 26-29 further define the amount of salicylic acid in the composition, most specifically wherein the composition comprises at least 0.5% w/w (claims 26-27) or less than 3% w/w (claims 28-29). As discussed above, *Singh et al* teach that "[s]alicylic acid has been approved by the U.S. Food and Drug Administration for the treatment of acne in concentrations of 0.5% to 2% by weight" (Column 1, Lines 16-17). Accordingly, claims 26-29 are *prima facie* obvious.

23. Instant claim 38 is drawn to the composition wherein the composition is in the form of a transparent gel. As stated by Hong et al, "conventional water-soluble polymers such as carboxmethylcellulose... are not proper materials to be used in hydroalcoholic gel compositions according to the present invention because they lose their viscosity or become cloudy" (Page 5, Lines 14-17). Accordingly, it is asserted that the hydroalcoholic gel composition obviated as discussed above would necessarily comprise a transparent gel.

24. **Claims 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Singh et al* (US 6,428,772), *Singh and Roberts* (JPET 268:144-151, 1993), *Hong et al* (WO 1999/39713), *Obata et al* (Int J Pharm 89:191-198, 1993), and**

***Loffler et al* (Household and Personal Products Industry, July 2002) as applied to claims 1 and 25 above, in further view of *Murad et al* (US 2002/0172719).**

25. Claims 30-34 are drawn to the composition which comprises one or more topically active ingredients useful in skin care, including hydrogen peroxide, which reads on claims 30-34. *Murad et al* teach compositions for the treatment and management of skin conditions such as acne comprising hydrogen peroxide (Abstract). As stated in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose… [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would have been *prima facie* obvious to include hydrogen peroxide in the composition.

26. Claims 35-37 further define the amount of hydrogen peroxide in the composition, most specifically wherein the composition comprises at least 1% w/w (claim 35) or less than 2% w/w (claims 36-37). *Murad et al* generically teach that "[a]dvantageously... the hydrogen peroxide is present in an amount from 0.01 to 6 weight percent" (Paragraph 0024), and specifically disclose an embodiment wherein hydrogen peroxide is present in 1.5% by weight (Paragraph 0068, Example 2). Accordingly, claims 35-37 are rejected as *prima facie* obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-

5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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